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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicant : Jackson Streeter
Appl. No. : 10/700,355
Filed : November 3, 2003
For : ENHANCEMENT OF IN VITRO
CULTURE OR VACCINE PRODUCTION
USING ELECTROMAGNETIC ENERGY
TREATMENT
Examiner : Taeyoon Kim

Group Art Unit: 1651

DECLARATION OF JACKSON STREETER, M.D. PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Jackson Streeter, M.D., declare as follows:

1. I am the sole inventor of the claimed subject matter of the above-captioned patent application.
2. I have reviewed the above-captioned patent application, including: the specification, the as-filed claims, and the pending claims as amended in the "Amendment and Response to July 25, 2006 Office Action" submitted herewith. I have also reviewed the July 25, 2006 Office Action in the above-captioned patent application, and the references cited therein, including U.S. Patent No. 6,063,108 issued to Salansky *et al.* ("Salansky") and van Brugel *et al.*, "*Power Density and Exposure Time of He-Ne Laser Irradiation Are More Important Than Total Energy Dose in Photo-Biomodulation of Human Fibroblasts In Vitro*," Lasers in Surgery and Medicine, Vol. 12, pp. 528-537 (1992) ("van Bruegel").
3. Vaccines are antigenic preparations introduced into a host body to establish immunity to a disease. When introduced into a host body, a vaccine triggers the host body to produce antibodies which correspond to the vaccine. Vaccines may be living and attenuated virus or bacteria cells, killed cells, inactivated cells, cell fragments, or inactivated, toxic compounds derived from cells.

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4. Persons skilled in the art of vaccine production understand that *in vitro* cell cultures can be used to produce cells or cell fragments to be used as a vaccine or to produce cells which produce compounds to be used as a vaccine. For example, as described in the above-captioned patent application at paragraph [0003]:

Important uses of cell culture[s] include the culturing of bacteria or hybridomas for the large-scale production of macromolecules such as antibodies or other proteins that are useful as biotechnological drugs, the culturing of bacteria useful for vaccines, and culturing of animal cells containing viruses useful for biotechnology or vaccines.

5. Persons skilled in the art of vaccine production understand that for vaccines which comprise cells (live and attenuated, dead, or inactivated) or cell fragments to be introduced into a host body, accelerating the production of a vaccine can be achieved by increasing the number of cells produced by the cell culture within a given amount of time. Persons skilled in the art of vaccine production also understand that for vaccines which comprise inactivated toxic compounds to be introduced into a host body, accelerating the production of a vaccine can be achieved by either increasing the number of toxic-compound-producing cells produced by the cell culture within a given amount of time or by increasing the amount of toxic compound produced by the cells of the cell culture. For example, as described in the above-captioned patent application at paragraph [0004]:

light energy applied to a culture enhances or improves the cell culture such as by providing for enhanced and accelerated formation of important biological macromolecules ... and also providing for accelerated cellular replication and an enhancement or prolongation of the life of cells so treated. Methods disclosed in accordance with the preferred embodiments herein may be used to accelerate the production of vaccines and/or other important products containing biological materials.

Furthermore, paragraph [0021] of the specification states: "By enhancing or improving the cell culture, the production of the products derived from the cell culture is also enhanced or accelerated, such products being useful as drugs, vaccines, and the like."

6. While there are different types of vaccines and different ways to accelerate the production of a vaccine using an *in vitro* cell culture, persons skilled in the art of vaccine production would understand the phrases "accelerating the production of a vaccine" and "providing an *in vitro* cell culture comprising cells useful in production of a vaccine" and would not find these phrases to be confusing or indefinite.

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7. The specification of the above-captioned patent application, including but not limited to the passages cited above, provides sufficient information for a person skilled in the art of vaccine production to understand that "accelerating the production of a vaccine" includes increasing the yield of the cell culture by: (i) increasing the replication of cells of the cell culture, (ii) increasing the lifetimes of cells of the cell culture, and/or (iii) increasing the amount of a vaccine compound formed by cells of the cell culture.

8. The specification of the above-captioned patent application, including but not limited to the passages cited above, provides sufficient information for a person skilled in the art of vaccine production to understand that "providing an *in vitro* cell culture comprising cells useful in production of a vaccine" includes providing a *in vitro* cell culture which comprises: (i) cells or cell fragments which can be introduced into a host body to trigger production of antibodies by the host body, and/or (ii) cells which produce compounds which can be introduced into a host body to trigger production of antibodies by the host body.

9. Salansky describes a method of *in vivo* light therapy for various maladies. For example, Salansky at column 27, lines 19-26 discloses that (emphasis added):

LEPT may also exert specific and non-specific effects on the immune system by affecting phagocytosis activation, modulation of reactive oxygen species release by neutrophilic granulocytes, neutrophil chemotaxis enhancement, T-lymphocyte blast transformation, T-Rosette formation activation, killer cell activation and alteration in blood levels of complement and immunoglobulins, including IgA, IgG and IgM.

The effects disclosed by Salansky are purely *in vivo* effects on the immune system of the subject undergoing therapy. Salansky does not disclose or suggest that the treated cells within the subject undergoing therapy would be useful in the production of a vaccine and does not disclose or suggest irradiation of cells *in vitro*. Persons skilled in the art of vaccine production would not understand Salansky to be disclosing or suggesting "providing an *in vitro* cell culture comprising cells useful in production of a vaccine" or "delivering an effective amount of electromagnetic energy to the *in vitro* cell culture."

10. Van Bruegel describes a study in which *in vitro* human fibroblast cells were irradiated by light having a wavelength of 630 nanometers from a He-Ne laser to affect collagen production. At page 528, first column, van Bruegel discloses that depending on the irradiation conditions, proliferation of the cells irradiated by 630 nanometer light was either positive or

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negative, and collagen production by the cells was either stimulated or inhibited. Van Bruegel does not disclose or suggest that the irradiated human fibroblast cells would be useful in the production of a vaccine and persons skilled in the art of vaccine production would know that such human fibroblast cells are not useful in the production of a vaccine. Persons skilled in the art of vaccine production would not understand van Bruegel to be disclosing or suggesting "providing an *in vitro* cell culture comprising cells useful in production of a vaccine." Furthermore, van Bruegel does not disclose or suggest that irradiating the human fibroblast cells with light having a wavelength of about 780 nm to about 840 nm would improve the human fibroblast cell culture.

11. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made upon information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001, Title 18 of the United States Code, and that willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 1/23/07 By: 
Jackson Streeter, M.D.

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